Universiy of La Verne Institutioanl Review Board Policy and Procedure on Udergraduate and Graduate Capstone Instructor Guidance
Approved June 4, 2019

Who is this document for?
This document is geared for instructors/faculty/staff/administration leading undergraduate or graduate capstone projects involving human subjects research.

Online Resources

The following website has been designed specifically to include most resources you will need to lead student research: https://laverne.edu/irb/mentorsadvisorschairssupervising-faculty/.

Current La Verne IRB Policies and Procedures

Activities in the context of specific courses, including undergraduate senior projects, graduate capstones, and classroom-wide projects involving human subjects research should comply with the federal guidelines under the supervision of the course instructor. For research activities that do not require La Verne IRB review and approval, the course instructor carries the responsibility to review and monitor the student(s) research for the protection of human participants and should adhere to all university and La Verne IRB policies when conducting research in a responsible and ethical manner (website for La Verne IRB policies: https://laverne.edu/irb/policies-and-procedures/.

All protocols that do not require La Verne IRB review are still required to be submitted to the La Verne IRBManager system for archival purposes (see Procedure for Instructor Approval of Student Protocols, below). Student research, along with all other research on campus, is subject to university policies regarding GDPR and other data security regulations' compliance, and/or misconduct, which can include not applying for La Verne IRB approval when necessary.

Note: if you are having students complete La Verne IRB forms as a classroom demonstration, nothing needs to be submitted to the La Verne IRB.

A Course Instructor Must Submit Student Protocols to the La Verne IRB for A Review By the IRB if:

They include empirical research with human participants and if the results are intended to be **published or presented** in professional/academic venues (and/or contribute to generalizable knowledge), which is per La Verne's Federal Wide Assurance with the Department of Health and Human Services.

Procedure and Timeline for La Verne IRB Review of Student Projects

The instructor will be listed as the PI on the protocol and the student will be listed as a co-investigator. Instructors are responsible for guiding the student through the process and ensuring the application and revisions are well-prepared and meet the expectations of La Verne IRB review. Further, the La Verne IRB requires instructors to be on all communication between the student and the La Verne IRB, and the instructor shall attempt to answer all questions before they are posed to the La Verne IRB.

The instructor and student should be aware of the time needed to gain approval for their project reviewed through the La Verne IRB. **Student applications should be submitted in the first month of the semester or before.** Depending on the type of review, and the preparedness of the protocol, the application can take a great deal of time to be approved by the La Verne IRB. **Exempt reviews are typically faster as they utilize a streamlined application.** Standard (full board) reviews are only conducted once a month and may require revision to be re-reviewed by the board at the meeting after the revisions are received (please review the description of the review process as it contains details of when to submit prior to the La Verne IRB meeting: https://laverne.edu/irb/expectations-of-ulv-irb-review-timeline/). The La Verne IRB will make every attempt to review and process student applications as fast as possible, **but reviews can and usually do take multiple months to gain approval and may not be approved within a single semester**.

Instructor Guidelines for Leading Student Research Protocols (Adapted from the University of Michigan)

1) Review student's plans for class, individual, or group projects, and suggest design improvements and ways to protect confidentiality and/or anonymity.

2) Require for the course that the student(s) complete CITI training, for the protection of human subjects in research. The **only accepted trainings** are the Social/Behavioral Basics/Refresher and Biomedical Basics/Refresher. Student trainings and Responsible Conduct of Research trainings **are not accepted although additional trainings may be needed for specific types of research (e.g., international research)**. Also, in some instances additional safety precautions and/or necessary certifications should be considered and provided to the La Verne IRB in the **Mentor Approved Application** (biosafety, laboratory safety, OHSA, etc.). **If working with vulnerable populations or sensitive data, the faculty instructor should be a specialist/expert in this area (as demonstrated through certifications and/or degrees) and have knowledge of proper research and safeguard protocols.**

3) Explain the components of informed consent/assent and information sheets. The templates on the La Verne IRB website (https://laverne.edu/irb/irb-forms-and-examples/informed-consent-forms-templates/) are required to be used. The required components defined by the policy on informed consent (https://laverne.edu/irb/wp-content/uploads/sites/28/2018/08/Informed-Consent-1.pdf) must be included. Please note,

a GDPR or other specific regulation-compliant informed consent may be needed in some instances. These are also available on the La Verne IRB website (https://laverne.edu/irb/irb-forms-and-examples/informed-consent-forms-templates/).

4) Explain the difference between anonymity and confidentiality and the necessity of being consistent throughout the study documentation, as the two words are not interchangeable. **Anonymous** means there is no identifiable information in the data that can be traced back to a specific individual, while **confidential** indicates identifiers are present in the data, but the researcher will not be sharing this information in a manner that can be traced back to a specific individual, thus protecting the participant.

5) Ensure extra protections for studies when students are considering researching participants who are part of vulnerable populations: these are studies that include vulnerable individuals identified in Subparts B-D of 45 CFR 46, which include pregnant women and fetuses, prisoners, and minors (under the age of 18). **Prisoners cannot be studied for student projects as they cannot be approved by the La Verne IRB and must be approved by a national entity.** Further, situational vulnerability must be considered (e.g., a non-vulnerable, middle aged male of middle class means gets rushed to the ER because of a stroke. While in his hospital bed, his medical doctor offers for him to be part of an experimental study for stroke patients).

   Examples of vulnerable populations include, but are not limited to, adults who are under legal guardianship, persons with intellectual or developmental disabilities, frail elderly, and low income when the study has a high incentive (The University of Virginia lists eight categories of vulnerability; refer to their website for specific examples (http://www.virginia.edu/vpr/irb/sbs/resources_guide_participants_vuln_eight.html).

   - **In a similar vein to UC Berkeley, the La Verne IRB strongly recommends that an undergraduate student who wants to study a vulnerable population instead communicates with spokespeople, representatives of the group, expert informants, and/or professionals who work with the community. Secondary public use data on the populations is also highly recommended.**
   - **Members of the vulnerable group should not be asked sensitive questions where if the information were made public (i.e., through data breach) they would be at risk.**

   If working with vulnerable populations or sensitive data, the faculty instructor should be a specialist in this area (as demonstrated through certifications and/or degrees) and have knowledge of proper research and safeguard protocols for the subject matter.

6) Extreme caution and extra precautions should be exercised if students propose studies where participants are to be asked about sensitive behavior (e.g. depression, suicide, illegal behavior, drug or alcohol use, sexual activity or abuse, traumatic experiences, etc.). **If working with vulnerable populations or sensitive data, the**

faculty instructor should be a specialist/expert in this area (as demonstrated through certifications and/or degrees) and have knowledge of proper research and safeguard protocols.

NOTE: Our current general liability insurance coverage for class projects **does not cover research that may require licensed or certified professionals for projects that require additional expertise, e.g. a nurse for biomedical projects, a registered dietician for projects involving the administration of supplements or ingestion of food, a psychologist for sensitive subjects, etc**. Those class projects would be considered a clinical trial by our insurance provider, which are not covered under our current policy.

7) Explain ways in which students should be attentive to potential language and miscommunication problems in conducting research. Also, discuss the equitable selection of participants.

8) Teach students the necessity in using clear and concise language with specific details and to double-check the meaning to prevent legal consequences. This includes projects with materials (including informed consents) prepared in another language. An expert in the language(s) other than the student should verify the preparation of the materials in the other language(s). For more guidance, refer to the policy on translated materials (https://laverne.edu/irb/wp-content/uploads/sites/28/2018/08/La-Verne-IRB-Translation-Policy-1.pdf).

9) Consider **ALL** risks involved and ways to safeguard human subjects in the research setting and throughout the entire proposal. State the risks and safeguards in the consent form/information sheet.

Risks and Safeguards:

Informational: If confidential, the identity of participants may be known or participants might be embarrassed if their names are linked to responses. (Typically, this means risk is minimal; for non-sensitive surveys, provide abbreviated informed consent information – purpose of study, student and faculty contact information. For sensitive surveys, provide more detailed informed consent information and switch to an anonymous research design). Anonymous surveys lower this risk. **Safeguards**: if confidential, tell the participants in the consent form/information sheet their data will be protected securely and describe how (e.g., Paper forms: locked in a stationary cabinet in researcher's non-University of La Verne Office).

Psychological: sensitive or discomforting questions. These should not be more than what someone would encounter in daily life. If it is, this increases the risk to high. **Safeguards**: 1) for student participants: include contact information for CAPS in the consent/information sheet (the researcher(s) are required to notify CAPS and receive acknowledgement before beginning research); for non-student

participants: 3 community counseling referrals, 2) conduct research via email or in a controlled setting (classroom or laboratory with faculty oversight; include debriefing if particularly sensitive data are collected), and 3) consider use of previously used survey instruments (with permission) where wording has already been tested.

Physical: potential harm or stress. For example, risks should not exceed what would be part of a typical physical education class or experiential learning exercise. **Safeguards**: Projects examining ingestion must have a supervising registered dietician, other studies that involve physical risk should have specialists who can mitigate those risks, supervising medical doctors, etc. **NOTE:** Our current general liability insurance coverage for class projects **does not cover research that may require licensed or certified professionals for certain projects that require additional expertise, e.g. a nurse for biomedical projects, a registered dietician for projects involving the administration of supplements or ingestion of food, a psychologist for sensitive subjects, etc**. Those class projects would be considered a clinical trial by our insurance provider, which are not covered under our current policy.

Social Group: social group risk relates to participants being members of or part of a group and having that relationship impacted by participating or not in the proposed research. For example, if a professor wants to conduct research on his/her students the students at La Verne may be at risk and should be told in the informed consent/information sheet that by participating or not in the research study, nor the content of their answers, will their relationship with La Verne and the professor be jeopardized in any way, along with their grades (this is a **safeguard**). Another typical scenario for social group status risk is the use of employees in research and participation, which may jeopardize their employment status.

10) If you are qualified, explain ways in which students should be attentive to the posing of sensitive questions, including topics related to sexual activity, victimization, use of alcohol or illegal drugs, or involvement in illegal activity. If you do not specialize in such an area, the student should change their research emphasis or consult an instructor with specific expertise in that area to ensure proper communication. **NOTE:** Under Title IX **all faculty, staff, student workers, etc. are mandatory reporters of sexual misconduct**. Therefore, any non-anonymous research where sexual misconduct is reported would require the instructor to report the sexual misconduct to the Title IX Coordinator for La Verne. **The mandatory reporting needs to be disclosed to all participants in the informed consent and gone over with the participants prior to participation.**

11) If the students propose working with residents of the European Economic Area (EEA) for their research project, you will ensure **all** GDPR procedures will be followed and take responsibility for making sure EEA resident inquiries are addressed immediately as per the international research policy (https://laverne.edu/irb/wp-

content/uploads/sites/28/2018/10/La-Verne-IRB-International-Research-GDPR.pdf), in order to ensure the avoidance of a minimum fine of 2-4% of the gross domestic product of the United States. If students are not proposing to work with EEA residents, they **must** clearly write their study population (e.g., Americans) in their consent forms/information sheets. These general rules for working with EEA populations will also apply to other populations through forthcoming personal data regulations for various states and countries. As these regulations go into effect they will be announced on the La Verne IRB website and linked to the Instructor webpage.

12) Suggesting, as much as possible, anonymous data collection so data is not linked to individuals. If there is information identifying individuals, suggest ways to keep identifying information separate from responses and the data protection policy from the La Verne IRB is followed (see step 13).

13) Requiring the student to collect the minimum demographic and sensitive information possible for their study to be practicable; the fewer data stored, the lower the risk.

14) Following storage procedures required by the La Verne IRB: https://laverne.edu/irb/wp-content/uploads/sites/28/2018/09/La-Verne-IRB-Data-Protection-Policy-Updated-Sept-2018.pdf

15) Verifying the students **are not planning to conduct a raffle**. Raffles require the advanced purchase of tickets, the raffle registered with the State of California at least 60 days prior to the raffle, along with other requirements that student and faculty research projects do not meet. **Do not allow the word raffle to be used in any of the research documents as it makes the university and instructor liable for violating California law.** For more information, refer to this website: https://blink.ucsd.edu/sponsor/advancement/advancement-services/gift-processing/list/raffles.html

16) Evaluating compliance with CA law of opportunity drawings. Students may conduct an **opportunity drawing in increments under $24.99** (over that amount and tax forms will need to be completed in order to report the funds as income to the IRS). **California law requires that opportunity drawings have "general and indiscriminate distributing of tickets."** For the La Verne IRB, we interpret this to mean the drawing is open to all who want to join and not just people who participate in your study. **Verify the informed consent/information sheet should account for this portion of the law (e.g., not stating the drawing is restricted to participants).**

17) Make sure the student obtains all necessary permissions to conduct their research, including permissions from non-La Verne entities at which the research will be conducted, etc.

18) Consider if there any potential problems if the research goes public. If so, the research will need to be adjusted for the students' skill level to avoid issues that could affect the university.

19) Confirm with the appropriate college Dean that additional insurance coverage is not needed for higher risk projects, such as those involving ingestion of any sort, off-campus events (e.g., teaching an exercise class at a local gym), admission of guilt for crimes, admission of sexual misconduct, genetics testing, etc. The Dean will decide if the project can proceed as proposed and suggest any changes to mitigate risk. **NOTE: genetics testing through an entity other than a University of La Verne lab is not coverable by our insurance carrier.**

Procedure for Instructor Approval of Student Protocols in IRBManager

If you approve **individual student (graduate or undergraduate) projects** as the instructor, the following steps must be followed:

1) the student will complete the Mentor Approved IRB Application in IRBManager (accessible at laverne.my.irbmanager.com) and an informed consent (if applicable), which can be found at: https://laverne.edu/irb/irb-forms-and-examples/informed-consent-forms-templates/.

2) The students will revise and update the application and documents until you approve their content.

3) The Mentor Approved applications in IRBManager are archived without formal La Verne IRB review as it is assumed the instructor is taking responsibility for the project(s). In the future, copies of the Mentor Approved applications will likely be sent to the appropriate college Dean, as well. For students, an example of the Mentor Approved Application, along with step-by-step guides and tutorials for completing the form can be found on the La Verne IRB website: https://laverne.edu/irb/students/. For instructors, the guides can be found at: https://laverne.edu/irb/mentorsadvisorschairssupervising-faculty/

4) The student and instructor will update the La Verne IRB or appropriate college Dean with any significant changes in risk to human participants throughout the course project as the changes may make the research subject to GDPR, other regulations, or misconduct policies.